

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellant(s): Kuslys et al.

Appl. No.: 10/088,766

Conf. No.: 2286

Filed: June 20, 2002

Title: COMPOSITION COMPRISING CASEIN PROTEIN AND WHEY PROTEIN

Art Unit: 1645

Examiner: J. Hines

Docket No.: 112701-780

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated April 9, 2009 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated July 14, 2008 as noted in Appellants' Appeal Brief filed on December 5, 2008 for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejections of pending Claims 1, 3-4, 6-10 and 13-20 be reversed.

II. THE REJECTION OF CLAIMS 1, 3-4, 6-10 AND 13-20 UNDER 35 U.S.C. § 103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE CITED REFERENCES

Appellants respectfully request that the Board reverse the rejection of Claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to *Yonekubo* and *Georgi*. Appellants respectfully submit that, even if combinable, the cited references fail to disclose each and every limitation of the present claims. Furthermore, one of ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

a. The combination of *Georgi* and *Yonekubo* fails to disclose or suggest a milk protein comprising 5% or more of tryptophan

Appellants respectfully submit that the cited references fail to disclose every element of the present claims. Independent Claims 1, 13 and 20 recite, in part, a composition comprising whey protein, wherein the whey protein is hydrolysed sweet whey protein from which casein-glyco-maclopeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan. Similarly, independent Claim 10 recites, in part, a method of producing an infant formula, the method comprising blending whey protein, wherein the whey protein is hydrolysed sweet whey protein from which casein-glyco-maclopeptide has been removed, and casein protein together with free arginine; free histidine; a milk protein comprising 5% or more of tryptophan and homogenising the blended mixture.

In contrast, the cited references fail to disclose a milk protein comprising 5% or more of tryptophan. For example, the Examiner acknowledges that *Georgi* fails to teach a milk protein comprising 5% or more of tryptophan and instead relies on *Yonekubo* for the disclosure of the claimed element. See, Examiner's Answer, page 5, line 13-page 8, line 2. However, *Yonekubo* is entirely directed to compositions for an infant with an insufficient intake of essential amino acids and merely discloses a composition comprising whey protein, casein protein and essential amino acids. See, *Yonekubo*, page 2, lines 13-39; page 3, lines 1 and 27-30. Nowhere does

Yonekubo disclose a milk protein comprising 5% or more of tryptophan. Therefore, Appellants respectfully submit that the cited references fail to disclose a milk protein comprising 5% or more of tryptophan as required, in part, by independent Claims 1, 10, 13 and 20 and Claims 3-4, 6-9 and 14-19 that depend therefrom.

1. Contrary to the Examiner's assertion, whey protein is not a milk protein comprising 5% or more of tryptophan

In response to Appellants' arguments, the Examiner asserts that *Yonekubo* discloses the claimed milk protein merely because *Yonekubo* teaches that its composition comprises "natural milk proteins" such as whey protein. See, Examiner's Answer, page 9, lines 8-13. The Examiner further asserts that because whey protein comprises alpha-lactalbumin, which has a high tryptophan content, *Yonekubo* necessarily discloses a milk protein comprising 5% or more of tryptophan. See, Examiner's Answer, page 9, lines 12-17. However, Appellants respectfully submit that, contrary to the Examiner's assertion, whey protein is not a milk protein comprising 5% or more of tryptophan merely because it includes some alpha-lactalbumin. For example, beta-lactoglobulin has a much lower tryptophan content than alpha-lactalbumin (approximately 2%). See, International Patent Application No. WO/2008/052995 to De Roos et al. ("De Roos"), page 2, lines 8-10. Furthermore, beta-lactoglobulin comprises a much larger portion of whey protein (65%) than alpha-lactalbumin (25%). See, http://en.wikipedia.org/wiki/Whey_protein. Therefore, the large amount of beta-lactoglobulin results in a low overall tryptophan content in the whey protein of approximately 2.7%. See, <http://daviscofoods.com/fractions/alpha-beta.cfm>. As such, whey protein is not a milk protein comprising 5% or more of tryptophan.

2. Contrary to the Examiner's assertion, casein protein is also not a milk protein comprising 5% or more of tryptophan

The Examiner further asserts that *Yonekubo* discloses the tryptophan-rich milk protein casein. See, Examiner's Answer, page 5, lines 16-17. However, contrary to the Examiner's assertion, casein has a low tryptophan content of merely 1%. See, <http://www.casein.com/products.htm>; <http://en.wikipedia.org/wiki/Tryptophan> (stating that 600 g

of casein yields approximately 4-8 g of tryptophan); and <http://scitoys.com/ingredients/casein.html>. Likewise, sodium caseinate contains merely 1.1% of tryptophan. See, <http://www.americancasein.com/pdfs/Sodium%20Caseinate-M%20.pdf>. Therefore, casein is not a milk protein comprising 5% or more of tryptophan as required, in part, by the present claims.

3. Neither whey protein nor casein protein is a milk protein comprising 5% or more of tryptophan

Furthermore, Appellants respectfully submit that the whey protein and casein protein of *Yonekubo* cannot be the milk protein comprising 5% or more of tryptophan because the present claims expressly distinguish between whey protein, casein protein and the claimed milk protein. For example, Claims 1, 13 and 20 recite, in part, a composition comprising whey protein, casein protein and a milk protein comprising 5% or more of tryptophan. Moreover, Claim 10 recites, in part, blending whey protein and casein protein together with a milk protein comprising 5% or more of tryptophan. Thus, Appellants respectfully submit that the claimed milk protein is a separate and distinct component which is added to the whey protein and casein protein. As such, the claimed milk protein cannot be whey protein or casein protein.

The only milk proteins disclosed by *Yonekubo* are whey protein and casein protein. See, *Yonekubo*, page 2, lines 32-39; page 3, lines 1 and 16-22; page 4, lines 39-50; page 5, line 1. In fact, the only disclosure in *Yonekubo* of a “milk protein” at all is the recitation that its composition comprises “natural milk proteins and amino acids [as well as] fats, carbohydrates, minerals, vitamins and other nutrients.” See, *Yonekubo*, page 2, lines 9-11. However, *Yonekubo* subsequently discloses a composition comprising merely casein protein, whey protein, and several amino acids. See, *Yonekubo*, page 2, lines 32-39; page 3, line 1. As such, Appellants respectfully submit that the only “natural milk proteins” disclosed by *Yonekubo* are whey protein and casein protein. As discussed previously, those proteins are not rich in tryptophan and are distinct from the claimed milk protein. Therefore, Appellants respectfully submit that *Yonekubo* fails to disclose a milk protein comprising 5% or more of tryptophan in accordance with the present claims.

4. Contrary to the Examiner's assertion, the alpha-lactalbumin in the whey protein is not a milk protein comprising 5% or more of tryptophan

The Examiner asserts that “[i]t is irrelevant that beta-lactoglobulin comprises a larger portion of the whey protein, since the claims only [recite] a milk protein with 5% or more of tryptophan and alpha-lactalbumin meets that limitation.” See, Examiner's Answer, page 11, lines 8-10. However, as the Examiner admits, the alpha-lactalbumin is only present in the whey protein. See, Examiner's Answer, page 6, lines 3-6; page 9, lines 12-17. As discussed previously, the claimed milk protein is separate and distinct from the whey protein. Thus, Appellants respectfully submit that the alpha-lactalbumin in the whey protein cannot be a milk protein comprising 5% or more of tryptophan as required, in part, by the present claims.

5. Contrary to the Examiner's assertion, *Georgi* fails to disclose alpha-lactoferrin

The Examiner further asserts that *Yonekubo* teaches milk proteins such as alpha-lactoferrin, a well-known milk protein with a tryptophan content of 5% or more. See, Examiner's Answer, page 11, lines 12-14. However, the Examiner fails to cite support for such assertion in *Yonekubo*, and Appellants find no disclosure of alpha-lactoferrin anywhere in *Yonekubo*. Therefore, for at least these reasons, Appellants respectfully submit that *Yonekubo* and, thus, the cited references fail to disclose or suggest a milk protein comprising 5% or more of tryptophan in accordance with the present claims.

b. There exists no reason why the skilled artisan would combine *Yonekubo* with *Georgi* to arrive at the present claims because *Yonekubo* teaches away from *Georgi* and the present claims

Furthermore, Appellants respectfully submit that there exists no reason why the skilled artisan would combine *Yonekubo* with *Georgi* to arrive at the presently claimed subject matter because *Yonekubo* teaches away from *Georgi* and the present claims. For example, Appellants submit that the cited combination would render *Yonekubo* unsatisfactory for its intended purpose. If the proposed modification would render the prior art invention being modified unsatisfactory

for its intended purpose, then there is not only no suggestion or motivation to make the proposed modifications, but the references also teach away from each other. See MPEP § 2143.01.V.

Yonekubo is entirely directed to providing essential amino acids to infants who do not receive a sufficient intake of essential amino acids due to existing nutritional or health disorders. See, *Yonekubo*, page 2, lines 13-24. *Yonekubo* combines whey protein with the amino acids merely to make the composition more palatable. See, *Yonekubo*, page 3, lines 5-10. In addition to the whey protein, *Yonekubo* specifically includes additional threonine as one of the essential amino acids of its composition. See, *Yonekubo*, page 3, line 1 (disclosing L-threonine weight percentage); page 4, line 47 (disclosing the amount of L-threonine added to a preparation).

In contrast, *Georgi* teaches providing a whey protein whose glyco-macropептиde (“GMP”) has been partially or completely removed. For example, *Georgi* is directed to a milk baby food containing a whey protein whose GMP has been partially or completely removed in order to reduce the threonine content of the baby food. See, *Georgi*, Abstract; column 1, lines 66-67; column 2, lines 1-3. The entire purpose of *Georgi* is to provide a formula with a reduced threonine content. See, *Georgi*, column 1, lines 42-44. Thus, substituting the whey protein of *Yonekubo* with the GMP-removed whey protein of *Georgi* would reduce the amount of essential amino acid threonine in the composition, thus rendering *Yonekubo*’s composition unfit for its intended purpose of providing essential amino acids to infants with existing nutritional or health disorders.

Moreover, *Yonekubo* teaches away from the whey protein of *Georgi* and the present claims. Like *Georgi*, the present claims recite a hydrolysed sweet whey protein from which caseino-glyco-macropептиde has been removed. However, as discussed previously, *Yonekubo* is entirely directed to providing essential amino acids such as threonine to infants with an insufficient intake of such amino acids. See, *Yonekubo*, page 2, lines 13-24. In fact, *Yonekubo* discloses not only using whey protein which already includes threonine, but further adding additional threonine in its free form to the composition. See, *Yonekubo*, page 3, line 1; page 4, line 47. As such, Appellants respectfully submit that *Yonekubo* teaches away from a whey protein with a reduced threonine content and, thus, one of skill in the art would not substitute the hydrolysed sweet whey protein of *Georgi* with the composition of *Yonekubo* to arrive at the present claims.

1. The Examiner has failed to consider the references as a whole, including those portions teaching away from each other and the claimed combination

In response to Appellants' arguments, the Examiner asserts that one of ordinary skill in the art would be motivated to modify the compositions of *Yonekubo* because *Georgi* teaches that removing GMP from infant compositions can help prevent hyperthreoninemia. See, Examiner's Answer, page 12, lines 1-7. However, Appellants respectfully submit that the Examiner has failed to consider the references as a whole, including those portions of the references teaching away from each other and the claimed combination. While *Georgi* teaches that removing GMP from infant compositions is generally beneficial for most infants, the Examiner has failed to acknowledge that *Yonekubo* is not directed to infant compositions such as *Georgi* which are intended for normal, healthy babies. See, *Georgi*, column 1, lines 1-45. Instead, *Yonekubo* is entirely directed to compositions which provide essential amino acids such as threonine to infants with an insufficient intake of such amino acids. See, *Yonekubo*, page 2, lines 13-24; page 3, line 1. Threonine is an essential amino acid which provides beneficial effects such as "promot[ing] normal growth by helping to maintain the proper protein balance in the body [and] support[ing] cardiovascular, liver, central nervous, and immune system function." See, <http://www.vitaminstuff.com/amino-acid-threonine.html>. Therefore, some threonine is necessary for infants. As a result, *Yonekubo* specifically teaches providing threonine, in addition to the threonine in its whey protein, to infants who suffer disorders that create an insufficient intake of amino acids. See, *Yonekubo*, page 2, lines 13-24; page 3, line 1. Thus, Appellants respectfully submit that, while removing GMP from infant formulas may be beneficial to infants who are already receiving a sufficient intake of amino acids, *Yonekubo* teaches away from reducing the threonine content in its whey protein because it is directed to providing additional amino acids to infants with nutritional disorders.

2. Contrary to the Examiner's assertion, the claimed combination was not known or obvious in the art

The Examiner further asserts that preferred embodiments do not constitute a teaching away of broader disclosures and that known compositions do not become patentable merely

because they are described as somewhat inferior. See, Examiner's Answer, page 12, lines 13-18. However, the *Gurley* case cited by the Examiner involved a prior art reference which disclosed the entire claimed combination but merely described it as inferior. See, *In re Gurley*, 27 F.3d 551, 552-53 (Fed. Cir. 1994). Unlike the reference in *Gurley*, the prior art cited by the Examiner does not disclose the claimed combination of elements and merely describe it as inferior. Instead, the Examiner has pieced together the teachings of *Yonekubo* and *Georgi* to arrive at the claimed combination. See, Examiner's Answer, page 7, lines 2-7; page 8, lines 3-9. As such, Appellants respectfully submit that the cited holding in *Gurley* is inapplicable to the present claims. Furthermore, *Gurley* expressly recognized that the Examiner must consider those portions of a reference which teach away from the claimed combination. See, *Gurley*, 27 F.3d at 553. As discussed previously, *Yonekubo*'s disclosure of providing additional threonine to an infant with an insufficient intake of such amino acid teaches away from the whey protein of *Georgi*.

3. Although the need for reduced threonine does not equate to compositions with no threonine, *Yonekubo*'s use of additional threonine with its whey protein teaches away from substitution with the reduced-threonine whey protein of *Georgi*

The Examiner asserts that *Yonekubo* does not discount the use of hydrolysed sweet whey protein from which GMP has been removed because the need for reduced threonine levels does not equate to compositions with no threonine content. See, Examiner's Answer, page 12, lines 19-22. However, as discussed previously, the mere disclosure in *Yonekubo* of combining additional threonine with its non-GMP-removed whey protein that already has a high threonine content teaches away from whey proteins that contain reduced levels of threonine. If *Yonekubo* were directed to providing a reduced level of threonine, it would not disclose the use of additional threonine when its whey protein already contains a high threonine content. Thus, by expressly disclosing the addition of more threonine to its whey protein which already contains a high level of threonine, *Yonekubo* would negate the effects of a reduced threonine whey protein as taught by *Georgi*.

4. Contrary to the Examiner's assertion, *Yonekubo* would not have been concerned with hyperthreoninemia because it is entirely directed to compositions for infants with an insufficient intake of amino acids

The Examiner also asserts that *Yonekubo* would be concerned with hyperthreoninemia because such condition results when high threonine levels cause the formation of too much urea in the body. See, Examiner's Answer, page 13, lines 6-13. However, Appellants respectfully submit that *Yonekubo* is not concerned with hyperthreoninemia because that condition only occurs when there is an excessive amount of the amino acid threonine. In contrast, *Yonekubo* is entirely directed to infants with disorders that result in an insufficient intake of amino acids such as threonine. See, *Yonekubo*, page 2, lines 13-24; page 3, line 1. The compositions of *Yonekubo* thus address the need to increase the amount of essential amino acids such as threonine to compensate for the lack of such amino acids in the infants' diet. See, *Yonekubo*, page 2, lines 13-24; page 4, line 47.

In sum, the Patent Office has failed to consider the cited references as a whole including those portions teaching against or away from each other and/or the claimed invention. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443, 448-49 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the [Appellant]." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009, (Fed. Cir. 1998). Because *Yonekubo* teaches away from *Georgi*, and the proposed combination would render *Yonekubo* unsatisfactory for its intended purpose, one of ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

For at least the reasons discussed above, the combination of *Yonekubo* and *Georgi* fails to teach, suggest, or even disclose all of the elements of Claims 1, 3-4, 6-10 and 13-20. Moreover, one of ordinary skill in the art would have no reason to combine the cited references because *Yonekubo* teaches away from *Georgi* and the present claims. Therefore, Appellants respectfully submit that Claims 1, 3-4, 6-10 and 13-20 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

Accordingly, Appellants respectfully request that the obviousness rejection with respect to Claims 1, 3-4, 6-10 and 13-20 be reconsidered and withdrawn.

III. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the Final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the obviousness rejections with respect to Claims 1, 3-4, 6-10 and 13-20.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-780 on the account statement.

Respectfully submitted,


BY

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157

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